PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M862-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP 03/12107	International filing date *(day/month/year)* 22.09.2003	Priority date *(day/month/year)* 24.09.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/202		
Applicant SUNTORY LIMITED ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.04.2004	17.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Greif, G Telephone No. +49 89 2399-8659

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP 03/12107

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-30 as originally filed

Claims, Numbers

1-35 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4,5,11,12,23,24,26-28
	No:	Claims	1-3,6-10,13-22,25,29-35
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-35
Industrial applicability (IA)	Yes:	Claims	1-35
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-6 080 787
D2: WO 96/10922 A
D3: US-A-6 034 130
D4: EP-A-1 239 022
D5: WO 96/21037 A
D6: US-A-4 668 704
D7: KOLETZKO B ET AL: "Polyunsaturated fatty acids in human milk and their role in early infant development." JOURNAL OF MAMMARY GLAND BIOLOGY AND NEOPLASIA. UNITED STATES JUL 1999, vol. 4, no. 3, July 1999 (1999-07), pages 269-284,
D8: CARLSON S E: "Docosahexaenoic acid and arachidonic acid in infant development." SEMINARS IN NEONATOLOGY: SN. ENGLAND OCT 2001, vol. 6, no. 5, October 2001 (2001-10), pages 437-449,
D9: AUESTAD NANCY ET AL: "Visual, cognitive, and language assessments at 39 months: a follow-up study of children fed formulas containing long-chain polyunsaturated fatty acids to 1 year of age." PEDIATRICS. UNITED STATES SEP 2003, vol. 112, no. 3 Pt 1, September 2003 (2003-09), pages e177-e183
D10 WILLATTS P ET AL: "Effect of long-chain polyunsaturated fatty acids in infant formula on problem solving at 10 months of age" LANCET, XX, XX, vol. 352, no. 9129, 29 August 1998 (1998-08-29), pages 688-691
D11 LUCAS A A ET AL: "Efficacy and safety of long-chain polyunsaturated fatty acid supplementation of infant-formula milk: a randomised trial" LANCET, XX, XX, vol. 354, no. 9194, 4 December 1999 (1999-12-04), pages 1948-1954

2. Novelty

2.1. The applicant is informed about the following passage of the PCT guidelines:
In interpreting claims for determining novelty, non-distinctive characteristics of a particular intended use (see claims 1, 6, 10, 13-18, 35: for example "with effects of decline prevention, improvement or enhancement of normal responses of cognitive abilities...") should be disregarded (Guidelines IV.-7.6). Hence, the

subject matter of claims 1, 6, 10, 13-18, 35 and claims dependent thereof discloses nothing more than the composition per se.

2.2. D1 discloses compositions comprising arachidonic acid, also in combination with another omega-3 polyunsaturated fatty acid, such as docosahexaenoic acid, whereby the compositions intend to deliver about 1.0 to about 60 mg/kg of arachidonic acid and about 0.25 to about 35 mg/kg of docosahexaenoic acid, or where the feeding of said compositions to an infant provide from about 5 to about 40 mg of arachidonic acid per day (claims 1-7, 16, 17, 25; column 13, lines 39-48). D1 anticipates the subject-matter of claims 1,2,6,13-21, and 29-35.
D2 discloses nutritional foods comprising fat mixtures characterized in that the content of arachidonic acid is 0.2 to 3 mg with respect to the total lipid content, and that the content of arachidonic acid and doxohexaenoic acid, present as triglycerides, consists of 0.05 to 1.5 weight-% with respect to the total amount of triglycerides. The arachidonic acid/docosahexaenoic acid ratio is 0,5:1 to 5:1 (claims 1-4; p. 4, line 5 - p. 5, line 34). Claims 1,2,6,13-21, and 29-35 lack novelty over D2.
D3 discloses synthetic lipid compositions comprising triacylglycerols which comprise, by weight, of 9-22% of polyunsaturated fatty acids, whereby less than 2% are arachidonic acid, and less than 1% comprises docosahexaenoic acid, with the ratio being 5:1 to 15:1; the arachidonic acid and docosahexaenoic acids are predominantly at the 2-position of the triacylglycerols, other acids comprise medium-chain fatty acids (column 2, lines 18-61; Example 1; Table 3; claims 1, 8). Claims 1-7 and 9-35 in their present form lack novelty over D3.
D4 discloses an oil in the form of triglycerides, whereby the fatty acids comprise arachidonic acid and docosahexaenoic acid. Said composition can be used as additive to infant formula (claims 1-3, 10-14). Claims 1, 2, 6, 33, 34 and 35 lack novelty over D4.
D5 discloses an oil produced by Mortierella alpina, said triglyceride oil having a high level of arachidonic acid residues (at least 40% of ARA in the triglyceride) whereby the composition is essentially free of eicosapenataneoic acid); said oil is used as an additive for infant formula or for the treatment of a neurological disorder (claims 1-34; p. 4, line 1 - p.5, line 14): Claims 1, 2, 6,7, 8, 9, 13-21, 33, 34, 35 are not novel over D5.
D6 discloses pharmaceutical compositions comprising a fatty acid selected from arachidonic acid and linoleic acid, present in concentrations from 10 to 200 mM, or in a dosage of 5mg/kg (column 2, lines 6-52). Claims 1, 6, and 33-35 lack novelty over D6.

D7 discloses fatty acid compositions of human milk, whereby the arachidonic acid is preferably located in the sn-2 and s-3 position of the triacylglycerol structure (p. 270, right column, 1st paragraph; Table 1). Claims 1, 2, 3, 6, 7, 10, 13-22, 25, 29, 30, and 33-35 lack novelty over D7.

3. Inventive Step

If the applicant would obviate the novelty-objections, his attention is drawn the following documents:

D8 states that arachidonic acid and docohexaenoic acid are present in high concentrations in cell membranes, and their presence in the diet has a potential influence on physiological functions, such as CNS functions (abstract, p. 437, left column, 1st paragraph, p. 438, "Effects of essential fatty acid deficiency on brain composition and function).

D9 states that docosahexaenoic acid and arachidonic acid are responsible for enhanced intellectual development in breastfed children (abstract).

D10 states that infants having been fed formula with arachidonic acid and docosahexaenoic acid have better problem-solving skills, relating to a higher IQ in later childhood (Table 1; p. 690, right column, lines 1-7.)

D11 states that breastfed children (having received arachidonic acid and docosahexaenoic acid) have higher cognitive scores than formula-fed infants (p. 1948, right column, 1st and 2nd paragraph).

All documents D8-D11 indicate that arachidonic acid and docosahexaenoic acid are essential for the development of brain function, and increases cognitive skills. The expert in the field would therefore expect to use the compositions disclosed in D1-D7 for the enhancement of cognitive function. An acknowledgement of inventive step is therefore not expected for the subject-matter of the present application.